CLAIMS

(1) An apparatus adapted to determine the binding affinity of a certain compound for a receptor, said apparatus comprising:

(a) A light source which generates and transmits a certain light signal; and

(b) An optical waveguide which receives said transmitted light signal in which an evanescent field is generated; and

(c) Processing means, connected to said light source and to said waveguide for using said evanescent field to determine said binding affinity.

(2) The apparatus of claim 1 wherein said receptor comprises estrogen receptor.

(3) The apparatus of claim 2 wherein said optical waveguide possesses a feature resembling an estrogen.

(4) The apparatus of claim 1 wherein said optical waveguide possesses a feature resembling at least a portion of a nucleotide resembling a certain nuclear response element to which said receptor binds.

(5) The apparatus of claim 4 wherein said nucleotide comprises a nuclear response element for an estrogen receptor

(6) The apparatus of claim 1 wherein said receptor further comprises a molecular tag which, when bound to said optical waveguide, produces an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field;

(7) The apparatus of claim 2 wherein said receptor is expressed in yeast.

(8) The apparatus of claim 1 wherein said optical waveguide comprises an optical fiber.

(9) The apparatus of claim 1 wherein said receptor further comprises a molecular tag which is an enzyme capable of acting upon a substrate so as to produce a chemical substance which when bound to said optical waveguide, produces an alteration in a certain characteristic of light collected from said waveguide.

(10) The apparatus of claim 1 wherein said receptor comprises progesterone receptor.

(11) The apparatus of claim 14 wherein said optical waveguide possesses a feature resembling a progestin

(12) The apparatus of claim 4 wherein said nucleotide comprises a nuclear response element for progesterone receptor

(13) The apparatus of claim 1 wherein said receptor comprises testosterone receptor.

(14) The apparatus of claim 16 wherein said optical waveguide possesses a feature resembling an androgen.

(15) The apparatus of claim 4 wherein said nucleotide comprises a nuclear response element for an androgen receptor

(16) A method to determine the estrogenic response associated with a certain test compound, said method comprising the steps of:

(a) Providing an evanescent sensor having an optical waveguide and a light source adapted to generate and transmit light to said optical waveguide; and

(b) Causing said optical waveguide to possess a molecular feature resembling estrone-3-glucuronide; and

(c) Tagging estrogen receptor with a fluorophore; and

(d) Creating at least one sample containing tagged estrogen receptor; and

(e) Creating at least one sample containing tagged estrogen receptor and said test compound; and

(f) Placing said evanescent sensor in contact with said solution containing tagged estrogen receptor; and

(g) Reading a first fluorescent signal emanating from said optical waveguide; and

(h) Placing said evanescent sensor in contact with said solution containing tagged estrogen receptor and said test compound; and

(i) Reading a second fluorescent signal emanating from said optical waveguide; and

(j) Using at least one pair of said first and said second fluorescent signals to determine said estrogenic response associated with said test compound; and

(17) The method of claim 16 wherein said optical waveguide comprises an optical fiber.

(18) A method to determine the progestinic response associated with a certain test compound, said method comprising the steps of:

(a) Providing an evanescent sensor having an optical waveguide and a light source adapted to generate and transmit light to said optical waveguide; and

(b) Causing said optical waveguide to possess a molecular feature resembling pregnanediol-3-glucuronide; and

(c) Tagging progesterone receptor with a fluorophore; and

(d) Creating at least one sample containing tagged progesterone receptor; and

(e) Creating at least one sample containing tagged progesterone receptor and said test compound; and

(f) Placing said evanescent sensor in contact with said solution containing tagged progesterone receptor; and

(g) Reading a first fluorescent signal emanating from said optical waveguide; and

(h) Placing said evanescent sensor in contact with said solution containing tagged progesterone receptor and said test compound; and

(i) Reading a second fluorescent signal emanating from said optical waveguide; and

(j) Using at least one pair of said first and said second fluorescent signals to determine said progestinic response associated with said test compound; and

(19) The method of claim 18 wherein said optical waveguide comprises an optical fiber.

(20) A method to determine the androgenic response associated with a certain test compound, said method comprising the steps of:

(a) Providing an evanescent sensor having an optical waveguide and a light source adapted to generate and transmit light to said optical waveguide; and

(b) Causing said optical waveguide to possess a molecular feature resembling testosterone-glucuronide; and

(c) Tagging testosterone receptor with a fluorophore; and

(d) Creating at least one sample containing tagged testosterone receptor; and

(e) Creating at least one sample containing tagged testosterone receptor and said test compound; and

(f) Placing said evanescent sensor in contact with said solution containing tagged testosterone receptor; and

(g) Reading a first fluorescent signal emanating from said optical waveguide; and

(h) Placing said evanescent sensor in contact with said solution containing tagged testosterone receptor and said test compound; and

(i) Reading a second fluorescent signal emanating from said optical waveguide; and

(j) Using said first and said second fluorescent signals to determine said androgenic response associated with said test compound; and

(21) The method of claim 20 wherein said optical waveguide comprises an optical fiber.

(22) An affinity determination assembly comprising:

(a) An optical evanescent sensor adapted to receive light, to internally reflect said received light, and to generate an evanescent field, said sensor possessing a molecular feature having a binding affinity for a certain biological receptor; and

(b) At least one dilution of a first solution containing biological receptor molecules said receptor molecules having been tagged with molecules which, when bound to said optical waveguide, produce an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field; and

(c) At least one dilution of a second solution containing a compound which is to be tested for binding to a biological receptor and further containing a certain quantity of said tagged biological receptor molecules; and

(d) A sensor cartridge which enables the surface of said optical evanescent sensor to selectively contact said first and said second solutions; and

(e) Processing means for measuring said certain characteristic of light collected from said optical waveguide in response to said generated evanescent field within said optical waveguide.

(23) A method of identifying compounds having potential for producing disruption of a biological regulatory system comprising the steps of:

(a) Providing An optical evanescent sensor adapted to receive light, to internally reflect said received light, and to generate an evanescent field, said sensor possessing a molecular feature having a binding affinity for a certain biological receptor; and

(b) injecting into at least one of said optical waveguide, light at or substantially near the critical angle of the waveguide in a sample; and

(c) providing at least one dilution of a first solution containing biological receptor molecules which have been tagged with molecules which, when bound to said optical waveguide, produce an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field; and

(d) providing at least one dilution of a second solution containing at least one compound which is to be tested to determine the potential of said compound for disrupting a biological regulatory system mediated by said biological receptor molecules, and further containing said tagged biological receptor molecules; and

(e) inserting at least one of said waveguides into at least one of pair of said first and said second solutions, measuring the response of said optical waveguide to said evanescent field while said waveguide is inserted into said first and said second solutions, whereby said measurements are used to identify said potential for disrupting a biological regulatory system.

(24) A binding measurement apparatus adapted to determine the impact of a test compound on binding of receptor molecules to response elements in a signal transduction mechanism involving said receptor molecules, said apparatus comprising:

(a) A light source adapted to generate a light signal; and

(b) an evanescent sensor in communication with said light signal, said sensor possessing a molecular feature which comprises a nucleotide resembling the nuclear response element for that receptor; and

(c) a sensor cartridge which enables the surface of said optical evanescent sensor to selectively contact test solutions; and

(d) at least one container having a concentration of tagged receptor molecules, said receptor molecules having been tagged with molecules which, when bound to said optical waveguide, produce an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field; and

(e) at least one container having a sample to be tested to which has been added a concentration of said tagged receptor molecules; and

(f) Processing means for measuring said certain characteristic of light collected from said optical waveguide in response to said generated evanescent field within said optical waveguide.

(25) A method of identifying compounds having potential for producing disruption of a biological regulatory system comprising the steps of:

(a) Providing at least one optical evanescent sensor adapted to receive light, to internally reflect said received light, and to generate an evanescent field, said sensor possessing a

molecular feature which comprises a nucleotide resembling the nuclear response element for that receptor; and

(b) injecting light into at least one of said optical waveguide at or substantially near the critical angle of the waveguide in a sample; and

(c) providing at least one dilution of a first solution containing biological receptor molecules said receptor molecules having been tagged with molecules which, when bound to said optical waveguide, produce an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field; and

(d) providing at least one dilution of a second solution containing at least one compound which is to be tested to determine the potential of said compound for disrupting a biological regulatory system mediated by said biological receptor molecules, in addition to a concentration of said tagged biological receptor molecules; and

(e) inserting at least one of said waveguide into at least one of said first and said second solutions, measuring the response of said optical waveguide(s) to said evanescent field while said waveguide(s) is inserted into said first and said second solutions, whereby at least one pair of said measurements are used to identify the potential of components of the second solution for disrupting a biological regulatory system.

(26) An apparatus of claim 24 wherein said molecular tag comprises an antibody having affinity for said receptor, said antibody having been tagged with molecules which, when bound to said optical waveguide, produce an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field;

(27) An apparatus of claim 24 wherein said molecular tag comprises a fluorescent molecule.

(28) An apparatus of claim 24 wherein said molecular tag comprises an enzyme capable of acting upon a substrate so as to produce a chemical substance which, when bound to said optical

waveguide, produces an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field.

(29) An apparatus of claim 24 wherein said receptor is the estrogen receptor and said nuclear response element is the estrogen response element.

(30) An apparatus adapted for *in vitro* assessment of anti-endocrine pharmaceutical for treatment of cancer of a type represented by a sample derived from a tumor tissue biopsy, said apparatus comprising:

(a) A light source adapted to generate a light signal; and

(b) At least one evanescent sensor in communication with said light signal, said sensor possessing a molecular feature which comprises a nucleotide resembling the nuclear response element for a biological receptor; and

(c) At least one of a second evanescent sensor in communication with said light signal, said sensor possessing a different molecular feature which has binding affinity for said biological receptor; and

(d) At least one sensor cartridge which enables the surface of said optical evanescent sensors to selectively contact test solutions; and

(e) at least one container having a concentration of tagged receptor molecules, said tagged receptor molecules producing an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field; and

(f) at least one container having a sample derived from a tumor tissue biopsy to which has been added tagged anti-receptor antibody, said tagged antibody an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field; and

(g) at least one container having a sample derived from a tumor tissue biopsy to which has been added tagged anti-receptor antibody, said tagged antibody producing an alteration in the response of said optical waveguide to said evanescent field, and to which has been added an anti-endocrine pharmaceutical which is to be assessed as a potential treatment for the cancer that is represented by said tumor tissue biopsy from which said sample is derived; and

(h) Processing means for measuring said certain characteristic of light collected from said optical waveguide in response to said generated evanescent field within said optical waveguide.

(31) A method of identifying anti-endocrine pharmaceuticals having potential for treating cancer represented by a sample derived from tumor tissue biopsy, comprising the steps of:

(a) Providing at least one optical evanescent sensor of claim 30; and

(b) Injecting light into said optical waveguide at or substantially near the critical angle of the waveguide in a sample; and

(c) Bringing at least one of said sensor cartridges into contact with said wild type receptor and measuring the response of said evanescent sensor to said evanescent field; and

(d) Bringing at least one of said sensor cartridges into contact with said sample derived from tumor tissue biopsy, said sample containing said tagged anti-receptor antibody, and measuring the response of said evanescent sensor to said evanescent field; and

(e) Bringing at least one of said sensor cartridge into contact with said sample derived from tumor tissue biopsy, said sample containing said tagged anti-receptor antibody, and in addition containing said anti-endocrine pharmaceutical, and measuring the response of said evanescent sensor to said evanescent field; and

(f) Comparing the response obtained in steps c, d, and e to determine whether the anti-endocrine pharmaceutical affected binding of receptor from said tumor tissue biopsy to said nuclear response element.

(32) An apparatus of claim 30 wherein said molecular tag comprises a fluorescent molecule.

(33) An apparatus of claim 30 wherein said molecular tag comprises an enzyme capable of acting upon a substrate so as to produce a chemical substance which when bound to said optical waveguide, produce an alteration in a certain characteristic of light collected from said waveguide in response to said generated evanescent field.

(34) An apparatus of claim 30 wherein said receptor is an estrogen receptor and said nuclear response element is an estrogen response element.

(35) An apparatus of claim 30 wherein said molecular feature of said second evanescent sensor comprises an anti-receptor antibody.

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